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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,224	08/09/2001	Timothy L. MacDonald	00399-12	3575

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EXAMINER
PATEL, SUDHAKER B

ART UNIT	PAPER NUMBER
1624	8

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/925,224	Applicant(s) Timothy L. Macdonald et al
	Examiner Sudhaker Patel	Art Unit 1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Feb 4, 2002

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-17 is/are pending in the applica

4a) Of the above, claim(s) 1-3 is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 4-17 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3,4,6,7

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims(in part) 4,5,6-8,9-17, drawn to compounds, simple composition, a method of use, and the first recited process of making composition of Generic Formula of Claim 4, classified in class 560, subclass 158,163.

II. Claims(inn part) 1-3,5-17, drawn to compounds, simple composition, a method of use, and the first recited process of making composition of Generic Formula of claim 1 wherein the core is: Substituted phenyl- 5-membered heterocycle 1,3-oxazol-2-one, classified in class 548, subclass various depending on the nature of variables R1,R3,R7,R8.

III. Claims(in part) 1-3,5-17, drawn to compounds, simple composition, a method of use, and the first recited process of making composition of Generic Formula is: Substituted phenyl-6-membered heterocycle 1,3-oxazin-2-one, classified in class 544, subclass various depending on the nature of variables.

Applicants are require to elect on of the above invention and a single species with exact and specific variables to be disclosed in reply to this Office Action.

2. The inventions are distinct, each from the other because of the following reasons: Inventions I-III are related as process of making and process of using the product. The use as

claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(I)).

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II-III, restriction for examination purposes as indicated is proper.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. This application contains claims directed to the following patentably distinct species of the claimed invention: Variations in variables R1,R3,R4,R7,R8 where applicable in phenyl, 1,3-oxazine or 1,3-oxazolidinone cores will generate species which are non-equivalent to each other.

Applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1,4,6,9,14 are generic.

Applicants are advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicants traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. During a telephone conversation with Mr. J.P. Breen on 10/16/01 a provisional election was made with traverse to prosecute the invention of Group I, claims(in part)4,5,6-8,9-17. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-3 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Since claims 6-17 link with other inventions, they will be examined bearing in mind the subject matter of Group I as elected by the applicants only. Applicants are urged to limit the scope of the claims and also to recheck the claim dependency in reply to this Office Action.

8. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Information Disclosure Statement

9. The information disclosure statement filed on 12/14/01; 1/10/02; 1/28/02; 2/4/02 fail to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Examiner has physically pulled out U.S.Patents and foreign patents from the resources made available to him.

Priority

10. This application discloses and claims only subject matter disclosed in prior Application Nos. 60119254 filed 2/9/99; 60136881 filed 6/1/99; 60137204, filed 6/2/99, and names an

additional inventor or inventors named in the prior application. Accordingly, this application may constitute a continuation or division. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78. Applicants are urged to take necessary actions to delete/amend the names, since the WO 0047202 application and all other applications which are either pending or expired have only 3 inventors.

Applicants' attention is also drawn to the fact that the copy of the WO reference as cited above has not been either disclosed &/or enclosed together with the IDS papers already submitted.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 09913075 & Sr. No. 10023059

both of which are undergoing "Preexam Processing" and are not available to examined for examination. Although the conflicting claims may or may not be identical, they are not patentably distinct from each other because their titles relate to derivatives of Felbamate as claimed herein.

Claim Rejections - 35 U.S.C. § 112

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-17 are rejected under 35 U.S.C. 112, second para, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

A). Claim 4, 5, 6 and claims dependent on these claims recite various provisos for R9, R1, R7, R8, R3, where applicable. If these provisos are intended to exclude certain prior art(s), applicants are urged to provide the copies of the same because the material is considered necessary for the examination.

B). Claim 6 which is independent and reciting all the 3 generic Formulae and claims " a method of treating a ..... a neurological disorder". It is not very clear as to what applicants want to accomplish. Clarification is requested for the neurological disorder.

C). Claim 9 which is also recited as an independent claim but citing all the 3 generic Formulae and compounds encompassed by the same claim " a method ....tissue damage resulting from localized hypoxic conditions". Clarity is requested.

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-17 are rejected under 35 U.S.C. 112 first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not give any guidance as to the method for treating a patient suffering from a neurological disorder or fro tissue damage resulting from localized hypoxic conditions which could be treated using instantly claimed step of administering a composition comprising a compound selected from claim 4 Formula.

In evaluating the enablement question, several factors are to be considered. In re Wands, 8 USPQ 2d 1400 (Fed. Cir. 1988); Ex parte Forman, 230 USPQ 546. The factors include:

(1). The nature of invention,

(2). the state of prior art,

(3). the predictability or lack thereof in the art,

(4). the amount of direction or guidance present,

(5). the presence or absence of working examples,

(6). the breadth of the claims,

(7). the quantity of experimentation needed, and

(8). the level of the skill in the art.

In the instant case, Applicants are claiming a method or a composition for treating neurological condition or tissue damage resulting from localized hypoxic conditions. The nature of the pharmaceutical art(s) is that it involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any medicinal or therapeutic regimen on its face. The instant specification does not give any guidance as to the full range of therapy involving use of modified Felbamate derivatives by using the instantly claimed step or process. In order to practice the claimed invention, one skilled in the art would have to speculate which disease could be treated by using the claimed derivatives found in the instant claim 4. The number of possible diseases &/or conditions embraced by the claims would impose undue experimentation on the skilled art worker. Therefore, the broad terminology is not enabled because the metes and bounds of the diseases which could be treated by using the derivatives found in the instant claims and the same can not be ascertained.

Applicants' attention is drawn to MPEP 806.05(h) which provides for one method of use to be examined with the elected compounds. A broad disclosure of utility as in the cited claims 6-10, 11-13 can not be deemed in compliance with 35 U.S.C. 112, first paragraph.

This requirement of one specific utility is also in compliance with 37 CFR 1.475 the unity of Invention Practice in International Applications and National Phase Applications under U.S.C. 371, and PCT Rule 13.2.

Therefore, applicants should limit the method claim to a sole "specific utility", and provide necessary supporting evidence for the same by appropriate tests which should include the corresponding reference compounds which are not fluorinated either of Felbamate family core or other compounds used for treating CNS &/or tissue damage resulting from localized hypoxic conditions and have toxic undesirable side efects.

Conclusion

Allowable Subject Matter

15. The following is a statement of reasons for the indication of allowable subject matter:

Claims(in part)4,5,6,7,8,9,10,14,15, 16,17 related to compounds if limited to elected invention of Group I only are allowable provided applicants can attend various issues raised in the above mentioned rejection.

The closest prior art reference Berger et al (U.S.P. 288444) and also Coffin et al (U.S.P. 5492930) teach making of 2-phenyl-1,3 propane diol dicarbamate and 2-phenyl-1,3-propanediol monocarbamate, their compositions, and use as anti-convulsant and treatment of CNS disorders or improving cognitive ability in mammal, whereas in the instantly claimed compounds have phenyl ring as well side chain hydrogen of -CH- group of propane substituted by Fluorine atoms respectively. Thus, the references '930 & ' 444 differ from the instantly claimed invention by not having Fluorine substitution on to the either phenyl or the propyl side chain of the cores. There is no teaching or indication of any kind to motivate anybody for arriving at the instantly claimed structure.

Therefore, the instantly claimed compounds deem to be novel and patentably distinct.

However, applicants' attention is brought the fact that the method of use claims are lacking supporting evidence for either less toxicity &/or superior unpredictable performance as already pointed out earlier together with rejections under 35 U.S.C. 112 as well double patenting rejections.

This application has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is, therefore, requested in promptly correcting any errors of which they may become aware in the specification.

Applicants are advised to provide the information related to instant application &/or similar &/or presently pending local or international applications, if any, related to the subject

matter included in the instant application to avoid various issues arising out of question of either double patenting &/or priority claims and other related matters.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhaker Patel, D.Sc. Tech. whose telephone number is (703) 308 4709.

The examiner can normally be reached on Monday thru' Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by the phone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah can be reached at (703) 308 4716.

A facsimile center has been established for Group 1600. The hours of operation Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or (703) 305-3592.

Any inquiry of general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308 1235.

Mukund J. Shah

Mukund Shah

sp

Supervisory Patent Examiner

February 24 , 2002.

Art Unit 1624